

from the body tissues and fluids across semipermeable membranes. Applied topically to the eye, a hypertonicity agent creates an osmotic gradient which draws water out of the cornea.

(h) *Isotonicity*. A state or quality in which the osmotic pressure in two fluids is equal.

(i) *Vasoconstrictor*. A pharmacologic agent which, when applied topically to the mucous membranes of the eye, causes transient constriction of conjunctival blood vessels.

Subpart B—Active Ingredients

§ 349.10 Ophthalmic astringent.

The active ingredient and its concentration in the product is as follows: Zinc sulfate, 0.25 percent.

§ 349.12 Ophthalmic demulcents.

The active ingredients of the product consist of any of the following, within the established concentrations for each ingredient:

- (a) Cellulose derivatives:
 - (1) Carboxymethylcellulose sodium, 0.2 to 2.5 percent.
 - (2) Hydroxyethyl cellulose, 0.2 to 2.5 percent.
 - (3) Hydroxypropyl methylcellulose, 0.2 to 2.5 percent.
 - (4) Methylcellulose, 0.2 to 2.5 percent.
- (b) Dextran 70, 0.1 percent when used with another polymeric demulcent agent in this section.
- (c) Gelatin, 0.01 percent.
- (d) Polyols, liquid:
 - (1) Glycerin, 0.2 to 1 percent.
 - (2) Polyethylene glycol 300, 0.2 to 1 percent.
 - (3) Polyethylene glycol 400, 0.2 to 1 percent.
 - (4) Polysorbate 80, 0.2 to 1 percent.
 - (5) Propylene glycol, 0.2 to 1 percent.
 - (e) Polyvinyl alcohol, 0.1 to 4 percent.
 - (f) Povidone, 0.1 to 2 percent.

§ 349.14 Ophthalmic emollients.

The active ingredients of the product consist of any of the following:

- (a) Lanolin preparations:
 - (1) Anhydrous lanolin, 1 to 10 percent in combination with one or more oleaginous emollient agents included in the monograph.
 - (2) Lanolin, 1 to 10 percent in combination with one or more oleaginous

emollient agents included in the monograph.

(b) Oleaginous ingredients:

- (1) Light mineral oil, up to 50 percent in combination with one or more other emollient agents included in the monograph.
- (2) Mineral oil, up to 50 percent in combination with one or more other emollient agents included in the monograph.
- (3) Paraffin, up to 5 percent in combination with one or more other emollient agents included in the monograph.
- (4) Petrolatum, up to 100 percent.
- (5) White ointment, up to 100 percent.
- (6) White petrolatum, up to 100 percent.
- (7) White wax, up to 5 percent in combination with one or more other emollient agents included in the monograph.
- (8) Yellow wax, up to 5 percent in combination with one or more other emollient agents included in the monograph.

§ 349.16 Ophthalmic hypertonicity agent.

The active ingredient and its concentration in the product is as follows: Sodium chloride, 2 to 5 percent.

§ 349.18 Ophthalmic vasoconstrictors.

The active ingredient of the product consists of one of the following, within the established concentration for each ingredient:

- (a) Ephedrine hydrochloride, 0.123 percent.
- (b) Naphazoline hydrochloride, 0.01 to 0.03 percent.
- (c) Phenylephrine hydrochloride, 0.08 to 0.2 percent.
- (d) Tetrahydrozoline hydrochloride, 0.01 to 0.05 percent.

§ 349.20 Eyewashes.

These products contain water, tonicity agents to establish isotonicity with tears, agents for establishing pH and buffering to achieve the same pH as tears, and a suitable preservative agent.